U.S. Environmental Protection Agency
CHILDREN'S HEALTH PROTECTION ADVISORY COMMITTEE
April 19–20, 2018
Holiday Inn Capitol
550 C Street SW, Washington, DC

– Meeting Summary –

On April 19 and 20, the Children's Health Protection Advisory Committee (CHPAC) met at the Holiday Inn Capitol in Washington, DC. [See Appendix A for the meeting agenda, Appendix B for a detailed update on the Office of Children's Health Protection (OCHP), and Appendix C for a list of the CHPAC members present.]

For copies of presentation handouts and slides from the meeting, please refer to the separate attachment titled "April 2018 CHPAC Presentations.pdf."

For questions regarding CHPAC, please contact the U.S. Environmental Protection Agency (EPA or the Agency) Designated Federal Official (DFO), Angela Hackel, at hackel.angela@epa.gov or at 202.566.2977.

I. Welcome, Introductions, and Review of Meeting Agenda

Barbara Morrissey, CHPAC chair, welcomed members, reviewed the objectives for the meeting, and gave an overview of the agenda for the plenary. Angela Hackel, EPA, introduced herself and reminded members of her role as the CHPAC DFO. CHPAC members, OCHP staff, and members of the public introduced themselves.

II. Review of Past CHPAC Letters: "Highest Priorities for Childhood Lead Exposure Prevention" and " Protecting Children's Health under Amended TSCA"

Tom Neltner, CHPAC member and workgroup chair, discussed the CHPAC letter "Highest Priorities for Childhood Lead Exposure Prevention." He began by reviewing the highest priorities CHPAC identified to further prevent childhood exposure to lead:

- Strengthen the Agency's Lead-Based Paint Hazards Standard for lead in paint, dust, and soil;
- Revise the Lead and Copper Rule to reduce lead in drinking water;
- Improve risk communication efforts to provide clarity and consistency;
- And encourage the Administration's infrastructure investment program to support healthy housing, childcare facilities, and schools and safe drinking water.

Tom noted that CHPAC received a response letter from Administrator Pruitt. Tom briefly reviewed the letter, highlighting the Agency's development of an updated Federal Strategy, which Administrator Pruitt expects to broadly address CHPAC's recommendations to protect children from health risks posed by lead.

Tom then described EPA's status on the four priorities CHPAC identified in their letter. In late June, EPA is expected to release a proposed Lead-Based Paint Rule to address risks of dust and paint. However, there is no plan for a proposed rule on soil. Tom then said that the Agency is committed to revising the Lead and Copper Rule this year, noting the possibility of a proposed rule being released in August. He

then touched on improvement of risk communication. EPA updated the informational pamphlet[1] given to people moving into homes built before 1978 to include information about potential exposure to lead via drinking water and the President's Task Force plans to include risk communication in the updated Federal Strategy. Tom concluded by addressing infrastructure. In an op-ed, Administrator Pruitt laid out his goals for infrastructure and specifically mentioned drinking water. However, Administrator Pruitt made no mention of childcare or housing as part of the infrastructure goals.

Following Tom's presentation, CHPAC members raised the following points:

- One CHPAC member asked if the informational lead pamphlet was translated into any other languages. Tom thought he saw an updated pamphlet in Spanish, but the EPA website could provide more information: https://www.epa.gov/lead/protect-your-family-lead-your-home.
- A member asked how the Agency's Lead-Based Paint Rule got to the Ninth Circuit Court. Tom said that petitioners filed with the Ninth Circuit Court arguing that EPA had unreasonably delayed on acting on a petition filed in 2009. The Ninth Circuit Court agreed with those petitioners and ordered EPA to move forward with the rule. A CHPAC member added that three of the petitioners were California residents, which the Ninth Circuit Court specifically referenced as why it had jurisdiction.
- A CHPAC member asked for Tom's opinion on the additions made to the informational lead pamphlet. Tom said that the updates to include the drinking water exposure information was a necessary fix, but in his opinion the edits could have gone further.

Barbara Morrissey, CHPAC Chair, discussed the CHPAC letter "Protecting Children's Health under Amended TSCA." She began by reviewing CHPAC's recommended methods and approaches for children's risk evaluation under TSCA. These recommendations were to use a life-stage approach, screen for developmental toxicants, and use biomonitoring data to inform exposure assessments. Barbara then described CHPAC's three recommended priorities for new methods and approaches to improve children's risk evaluations under the Toxic Substances Control Act (TSCA). The three crucial areas for Agency focus were children's exposure information, age-appropriate safety factors, and methods for identification and characterization of developmental toxicants.

Barbara noted that CHPAC received a response from Wendy Cleland-Hamnett, former Acting Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, affirming most of CHPAC's recommendations. EPA agreed with the recommendations to use a life-stage approach, screen for developmental toxicants when exposure of women of child-bearing age or children is likely, and use biomonitoring information when it is available. Barbara clarified that the Agency would consider age-appropriate safety factors, but did not agree to any default values. She said that, in terms of methods for the identification and characterization of developmental toxicants, EPA is considering a wide array of screening and alternative testing approaches to incorporate into the prioritization process.

Barbara described the actions taken by EPA in the rulemaking process for chemical risk evaluations under TSCA. EPA does not specifically require the use of the life-stage approach, but it is mentioned in some of the scoping documents for the risk evaluations of the first 10 chemicals designated in the amended TSCA, or the Frank R. Lautenberg Chemical Safety for the 21st Century Act. Barbara added that the use of the life-stage approach is something CHPAC will need to review when the problem formulation documents come out and noted the interest in forming a workgroup to undertake this review.

Following Barbara's presentation, CHPAC members raised the following points:

[1]The pamphlet is titled "Protect Your Family from Lead in Your Home" (sometimes referred to as the "Blue Book")

- One CHPAC member said that it is important for CHPAC to provide feedback on the draft problem formulations because the Agency is actively seeking advice. With the change in leadership after the election there have been some disagreements about the direction and approach the Agency is taking on implementing the new TSCA requirements. Because of this, some of the options being discussed by the Agency are inconsistent with the recommendations made by CHPAC.
- Barbara asked the CHPAC member if, aside from the conditions of use, legacy uses, and aggregate exposure, there were any other issues CHPAC should review. The CHPAC member replied that the prioritization process, specifically the kind of data the Agency will collect prior to initiating the prioritization of a chemical substance, is an issue that should be watched. The member added that there is a concern that the pressure to move new chemical substances through the review process could result in substances entering the market place with virtually no restrictions.
- Barbara asked the CHPAC member if there were any upcoming opportunities for public comments on new chemical substances under TSCA. The CHPAC member was unsure if anything new was close to being released for public comment.

III. Overview and Update of Novel Approaches in EPA's Endocrine Disruptor Screening Program (EDSP) with an Emphasis on Life Stages

Stan Barone, Acting Director, EPA Office of Science Coordination and Policy, presented on the Agency's Endocrine Disruptor Screening Program (EDSP). First he discussed the program's history. The 1996 amendments to the Food Quality Protection Act (FQPA) as well as the Federal Food, Drug, and Cosmetic Act and the Safe Drinking Water Act (SDWA) require EPA to "develop a screening program, using appropriate validated test systems and other scientifically relevant information to determine if certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen." The EDSP was established following the recommendations of the Endocrine Disruptor Screening and Testing Advisory Committee, public comments, and EPA's Science Advisory Board and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel. The EDSP evaluates estrogen, androgen, and thyroid hormones; human, fish, and wildlife; and pesticides, commercial chemicals, and environmental contaminants using a two-tiered approach:

- The Tier 1 test battery identifies potentially endocrine bioactive substances.
- Tier 2 testing evaluates the dose-response relationship and if the substance is endocrine bioactive.

The aim of the EDSP is to use computational tools and models to:

- Rapidly screen chemicals in the EDSP universe (i.e., 10,000 FIFRA and SDWA chemicals) for endocrine bioactivity,
- Contribute to the weight-of-evidence screening level determination of a chemical's potential bioactivity, and
- Provide alternative data for specific endpoints in the EDSP Tier 1 battery.

The EDSP has been driven by the need to screen thousands of chemicals more efficiently. The current Tier 1 battery of assays and Tier 2 tests are mainly *in vivo* tests, and the EDSP is working to develop high-throughput (HT) assays and computational models. Stan noted that it costs approximately $2 million to take one chemical through the current battery of assays. However, with the HT alternatives, the cost would be reduced by 90%.

The "pivot" to the EDSP is being implemented though adverse outcome pathway (AOP)/pathway elucidation, bioactivity model development, network model development, ESDP universe of chemicals

interrogation, and HT assay development. Its focus is a performance-based approach that focuses on the end result; allows for diverse methodology within the same use-context; uses performance-based acceptance criteria for relevant, reliability, and transparency to establish confidence in results; and allows for the quick adoption of scientific innovations.

Stan presented on the EDSP estrogen receptor (ER) pathway model, which is used to prioritize chemicals for testing and as an alternative to the low-throughput ER binding, low-throughput ER transactivation, and uterotrophic assays. He gave an overview of the 18 assays that are used to interrogate chemicals and the methods used to determine "true hits" of ER bioactivity. After testing the model with 45 reference chemicals, the results indicated the following:

- Out of 26 reference agonist chemicals, 2 very weak agonists were missed, potentially active only at >100 μM.
- Out of 12 reference negative agonist chemicals, all were negative.
- Out of 4 reference antagonist chemicals, all were positive.
- Out of 14 reference negative antagonist chemicals, 3 had non-zero values, but all were <0.05 AUC (area under the curve).

Stan noted that 89–97% of the "hits" for ER antagonism and agonism were on target.

Similar to the ER pathway model, the androgen receptor (AR) pathway model is used to prioritize chemicals for testing as an alternative to the low-throughput AR binding assay. The AR model uses 11 assays and was tested using 55 chemicals during a cross-laboratory validation effort and 54 reference chemicals under the EDSP Tier 1 test orders.

The cross-laboratory validation effort had the following results:

- Twenty-two of 24 actives were identified (the 2 that were missed were only active at high concentrations).
- The majority of inactives were identified as such (19/31), but 12 were called active (9 being estrogen active).
- A greater than 93% balanced accuracy for agonism and antagonism was achieved.
- The active reference chemicals that were missed were classified as "weak" or "very weak."

The EDSP Tier 1 test orders results included the following:

- Two of 9 actives were called active; all but one of the missed chemicals were active above the upper tested concentration.
- Twenty-four of 521 inactives were called active; 6 were active antagonists, but 4 had low confidence scores.
- Most of the Tier 1 positive chemicals were predicted as such; the missed positives were active at concentrations near to or higher than was tested in the AR assays.
- Good agreement with Tier 1 negative results was achieved; positives in the AR pathway model mostly had low confidence scores or were ER pathway actives.

Stan summarized the advantages of the ER and AR pathway models as:

- Covering more of the biological pathway than the *in vitro* assays;
- Being useful for rapid prioritization;
- Reducing animal use; and

- Saving potentially money, time, and resources.

The HT steroidogenesis assay is used to prioritize chemicals for testing and as an alternative to the low-throughput steroidogenesis assay. The HT assay, HT-H205R, considers four classes of steroids (i.e., estrogens, androgens, corticosteroids, and progestagens) and measures 11 hormone analytes, which provides a more robust and sensitive of steroidogenesis. Evaluation of the HT-H295R Assay indicated good concordance of results, with accuracies between 75–91%. There was minor disagreements between the low-throughput and HT assays among chemicals with borderline activity or activity at high concentrations.

The EDSP is also working to develop a thyroid hormone analysis framework. Stan discussed the role of thyroid hormones in adults, fetuses, and children and introduced the spectrum of neurological and other adverse outcomes associated with thyroid hormones. He also gave a brief overview of the thyroid pathway and the maternal-fetal thyroid network.

The EDSP has developed a conceptual network model to investigate adverse outcomes (AO) by developing assays for each molecular initiating event (MIE). These key events (i.e., MIEs) alter thyroid hormone levels and lead to various thyroid-related adverse outcomes (e.g., auditory impairments, thyroid tumors, young survival reductions, etc.). Stan underscored that not all of the pathways are connected; some key MIEs are only related to certain AOs and some are not. A single AO does not require all of the MIEs. He also noted that EPA is collaborating with partners outside the United States to push this effort forward, as there is much value to be added when considering upstream MIEs. The Agency aims to incorporate this to a larger degree within the next 2 to 3 years.

Finally, Stan reviewed the next steps for the EDSP, which include the following:

- Development and refinement of additional assays.
- Identification of reference chemicals for the current assays and newly-developed ones.
- Development of performance-based approaches.
- Development of an integrative strategy for analysis of assay.

Following Stan's presentation, CHPAC members raised the following points:

- A CHPAC member asked if the European Union (EU) is ahead of the United States in terms of characterizing hazards and risks. Stan responded that the United States is not behind. The EU's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) program is still evaluating the high volume of submissions they received. Stan also noted that the EU's regulatory approach is based on the precautionary approach, whereas our statutes are risk-based. Therefore, there are similarities between the United States and EU when it comes to determining bioactivity, but a divergence in the context of risk-based approaches.
- A member asked what the EDSP is trying to accomplish. Stan responded that the program is generating data that the Agency can consider in the context of prioritization. He added the discussion occurs not only between pesticide registrants, but other groups that may be interested in alternative compounds as well.
- A member inquired about the program deadline. Stan replied that the FQPA does not list deadlines other than the establishment of the Endocrine Disruptor Screening and Testing Advisory Committee. The FQPA outlined the timeline for developing the tiered approach, which the Agency was late on delivering. The FQPA did not mandate a timeline for the rest of the process, so it is up to the Agency to determine an efficient and practical timeline. The member asked if EPA has an internal schedule. Stan noted that the Agency outlined a plan in the 2015

comprehensive management plan and will report out again in 2020. In the meanwhile, progress depends on funding. The 2017–2018 budget was approved in full, but funding in 2019 is uncertain.

- A member stated that most animal testing guidelines have been standardized by the Organization for Economic Cooperation and Development (OECD). She asked if there will be a new OECD process using these new assays. Stan replied that there will be. He noted that many of the OECD member states use the EPA pubertal guideline. He added that there has not been an OECD validation process on that yet, as it is cumbersome and lengthy.
- A member commented that the AR pathway model was quite good at picking up actives, but also picked up more of the negatives as "hits" than the ER model did. Stan agreed, though he pointed out that the proportion of false negatives was <10%. EDSP is less concerned about false positives than false negatives from a health risk perspective.
- A member noted that the key effects in the thyroid hormone model are quite brief, and there is information to suggest that other effects should be included. Stan replied that there is, in fact, a range of responses, and the model is simplified. The member commented that she was struck by the fact that there was no mention of breastfeeding, which can have a critical impact on offspring. Stan noted that the program is aware that exposure occurs beyond birth, and there is an effort to link this AOP work with a physiologically based pharmacokinetic (PBPK) model as one way to address the issue.
- A member asked how the EDSP work will be used in Agency risk assessment. Stan pointed out that there are many different kinds of decision contexts within EPA, and EDSP is focused on prioritization (i.e., screening 10000–80000 chemicals). He added that in risk evaluation, the question is how to get from the half-maximal effective concentration (EC_{50}) *in vivo* or the half-maximal activity concentration (AC_{50}) *in vitro* to a biological concentration. In other words, how do we move from a concentration in a well plate to what is measured in serum, liver, or brain samples. Related to this, EDSP has been focusing on HT reverse toxicokinetics to develop the data and approaches to do just that. The member noted that absorption, distribution, metabolism, and excretion (ADME) are still not accounted for. Stan acknowledged this and added that PBPK models will consider these aspects.
- A member commented that the EDSP is a remarkable program and is a great step forward. He asked how the EDSP will expand its screening program if Congress mandates it. He followed by asking how many compounds can the program test in a year. Stan noted that the current Tier 1/Tier 2 process would require over 100 years. The program estimates that, with the proper funding, the HT approach would require only a few years. He added that they are nearing implementation for ER and AR, but the steroidogenesis and thyroid hormone assays need another 3–5 years for full development. The science is moving forward rapidly enough that the program could incorporate computational toxicology approaches in less time.
- A member noted that the program has undergone a huge amount of growth in the last 20 years. He also pointed out that the field is still advancing rapidly in the context of concurrent exposures and hormones related to obesity, for example. He asked whether Stan envisions the EDSP as a living program. Stan noted that, the program is moving away from the set tiered testing approach toward an approach based in systems biology. The member followed up by asking if EPA has published any papers on that process. Stan replied that EPA has published several papers on that topic. He gave an example of a paper on skin sensitization and noted that EDSP partners in the Office of Pesticide Programs have been successful in moving EPA's EU colleagues toward acceptance. He noted that this success is a harbinger of how EPA would like to work with them in the context of the ER/AR pathways as well. With regards to adding other hormone systems, Stan

explained that the program is always met with resistance when considering things "on the horizon," as the statutory authority was for estrogen. He added that the EDSP is currently looking at the new science, and he hopes the CHPAC will provide new information and the associated guidance to EPA as it is available.

- A member asked when the EDSP program will reach the point of identifying chemicals that should be pulled and if the program has a plan to avoid regrettable substitutions. Stan explained that when the program first started, industry removed 18 chemicals from the market voluntarily. He added that, in terms of the statutory mandate, EDSP has to make determinations based on endocrine disruption. The year 2020 is the due date for decisions on pesticide active ingredients in current use products. Stan noted that whether the pesticide determinations will consider endocrine disruption is a science policy question, which is not a decision he makes.
- A member asked how the EDSP's pathway models play into cumulative risk assessment. Stan responded that the quick answer is that reports from the National Academy of Sciences have expanded the concept of risk assessment from a common mechanism of action to framing around common adverse outcomes. The Agency has a discretionary authority to consider endocrine disruption in that context. However, the process is not finalized, but that is what the EDSP is working toward.
- A member mentioned the draft document on *in vitro* sensitization that is currently open for public comment, but suggests the test are so good that EPA should move forward with the process. She asked for clarification in the context of the false negatives and false positives that Stan discussed. Stan confirmed that the science policy statement that was released does say that the Agency will accept alternative tests for mouse lymph node assays for sensitization. This is built on years of validation efforts that show the alternative tests are better than the mouse lymph node assay, which was better than the previous rabbit assay. The idea is that there is a more relevant and predictive assay using computational models and predictive *in vitro* assays. He clarified that the policy was intended to notify scientists that they could submit these alternative data, even if they had previously agreed to submit the earlier assay data.

IV. CDC's Work on Lead Elimination

Sharunda Buchanan, Acting Director, Office of Priority Projects and Innovation in the Immediate Office of the Director, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (ATSDR), Centers of Disease Control and Prevention (CDC), discussed CDC/ATSDR's work on lead elimination. She began by reviewing the background of the Childhood Lead Poisoning Prevention Program (CLPPP). Sharunda highlighted the success of the program from the 1980s to 2010, noting improved surveillance and universal and targeted screening efforts. She then said that because Congress believed the CLPPP had achieved its mission of preventing childhood lead poisoning, the program was defunded in 2012, losing 93% of its funding. The program was reduced to providing technical assistance, and began to phase out its advisory committee and extramural program. Sharunda noted that in 2014 some funding was restored to the program, mainly to focus on surveillance activities and strategies to target high-risk children.

Sharunda described CDC's involvement in the response to the Flint Water Crisis. Through the response and subsequent investigations, it was clear that lead poisoning still posed a risk to children. In 2018, the CLPPP's funding was restored to the level of the 1990s and the program will be able to do more to eliminate childhood lead poisoning.

Sharunda then discussed some of the recent activities of the CLPPP. She explained three Notice of Funding Opportunities that the CLPPP developed, published, reviewed, and awarded in FY17. These funding opportunities will provide support and technical assistance to state and local programs to identify and evaluate children exposed to lead and will ensure appropriate follow-up services are administered.

She described the Lead Exposure and Prevention Advisory Committee (LEPAC), which was established under the Federal Advisory Committee Act by the Water Infrastructure Improvements for the Nation Act of 2016. Some of LEPAC's duties are to review federal programs and services available to individuals and communities exposed to lead and identify best practices regarding lead screening and the prevention of lead poisoning. In addition, the CDC is working to update the blood lead reference value. Sharunda also introduced a number of CDC crosscutting activities that are related to lead. Included in the list of activities were the National Institute of Occupational Safety and Health's Adult Blood Lead Epidemiology and Surveillance Program and the CDC's National Center for Emerging and Zoonotic Infectious Diseases Division of Global Migration and Quarantine's Refugee Screening Program.

Sharunda concluded her presentation by speaking about her work as a member of the Lead Subcommittee for the President's Task Force on Environmental Health Risks and Safety Risks to Children. She explained that the current priority activity of the Lead Subcommittee for 2017–2018 is to draft a new Federal Lead Strategy and Stakeholder Engagement. Sharunda hopes the collaboration between CDC and the other agencies and entities continues during the drafting and implementation stages of the new Federal Lead Strategy.

Following Sharunda's presentation, CHPAC members raised the following points:

- One CHPAC member asked for Sharunda's opinion on Puerto Rico. Sharunda responded that the CLPPP performed an investigation in Puerto Rico and found pockets of children with elevated blood lead levels due to recycled batteries. However, before the CLPPP could develop a strategy to help Puerto Rico, the CLPPP was defunded. When the CLPPP received additional funding, Puerto Rico did not apply for the funds. Sharunda noted that a post-hurricane Puerto Rico might be a good place to send additional support.
- A member noted that outbreaks of diseases such as Tuberculosis and Hanta Virus have occurred because their prevention programs have had their funding cut. He added that an extra sense of caution and vigilance needs to be applied to those budget decisions.
- One member asked if the blood lead reference value of 3.5 µg/dL is still being debated. Sharunda replied that at the CDC, the blood lead reference value of 3.5 µg/dL is not being debated, but it needs to be vetted by the CDC leadership.
- Several members noted that when the CDC finalizes the new blood lead reference value, it will be important to communicate with a number of groups, including health care professionals, environmental groups, and laboratories. Sharunda noted that the CDC is working closely with the American Academy of Pediatrics and the Association of Public Health Laboratories to develop a communication plan if the new blood lead reference value is released. She later added that the CDC will also reach out to nurses.
- A CHPAC member asked if there was a deadline for the new Federal Lead Strategy. Sharunda said that the goal is to release the new Federal Lead Strategy at the National Healthy Homes Conference on June 28, 2018.
- A member asked about other priority projects at CDC besides lead. Sharunda replied that water, both drinking and recreational water, is a priority issue for the CDC.
- A member commented that when revising the blood lead reference value, the laboratories that are hesitant to upgrade their instruments should not be able to hold up the process as much as they already have.
- One member asked what will have the biggest impact on the elimination of lead in the next 5–10 years. Sharunda answered that an increased focus on primary prevention by the CDC and its federal partners could significantly impact lead exposure reduction.

- A CHPAC member asked if the CDC will look at the effects of climate change. Sharunda explained that the CDC received additional funding this year to continue to investigate potential health effects associated with extreme weather events.
- A member noted that lead is an important environmental justice issue because some communities are more vulnerable than others. The member added that it will also be important to consider the aggregate exposure of lead, arsenic, and the other chemicals that may be found in susceptible populations.
- A CHPAC member said that some of ATSDR's accredited continuing medical educational materials related to lead are outdated. He noted specifically that the link to grand rounds references a level of concern of 10 µg/dL rather than 5 µg/dL, recommends chelation therapy at 45 µg/dL rather than 40 µg/dL, and does not touch on lead exposures in drinking water.
- One CHPAC member noted that a document produced by the CDC about lead exposure in pregnancy and lactation has not received any follow up, and many medical professionals, particularly in the obstetrics and gynecology community, are not aware of it. The member suggested that CDC provide outreach to practitioners on the document, since it was so well done and contains sought-after information. Sharunda said that she will look into outreach for the document.

V. Children's Health Risk Assessment

Brenda Foos, Director of the Regulatory Support and Science Policy Division, in EPA's Office of Children's Health Protection, presented on children's health considerations in Agency risk assessments. She began by defining human health risk assessment as "the process to estimate the nature and probability of adverse health effects in humans who may be exposed to chemicals in contaminated environmental media, now or in the future." She added that if children's risks are not included in risk assessment, it is unlikely they will be considered in the action the Agency takes as a result. Children require special consideration as they are not small adults. They have unique windows of vulnerability, physiological differences, and different environments.

Executive Order 1304, *Protection of Children from Environmental Health Risk & Safety Risks*, applies only to economically significant actions, but requires that each federal agency:

- shall make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children; and
- shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks.

EPA's Policy on Evaluating Health Risks to Children states that the Agency "consider the risks to infants and children consistently and explicitly as a part of risk assessments generated during its decision-making process, including the setting of standards to protect public health and the environment."

Brenda reviewed the steps in the risk assessment process at EPA. First, investigators must undergo problem formulation, where they scope out the question to be addressed. There are a number of life stage-specific considerations for children and pregnant women (e.g., different environments, physiological differences, and windows of vulnerability during development) that should be incorporated. Next, during hazard identification, the research team identifies, evaluates, and synthesizes information describing the associated health effects by answering questions such as:

- Are the outcomes cancerous and/or non-cancerous?
- Is the mode of action (MOA) known?
- What timeframe of exposure is harmful (i.e., acute, subchronic, chronic)?

- What data are available? What data are not available (e.g., animal, human, other)?

During the hazard identification process, researchers should consider whether there are toxicokinetic (i.e., ADME) or toxicodynamic (i.e., windows of development) differences at different life stages.

The next step in the risk assessment process is assessing the dose-response relationship. The approach is different for quantifying non-cancer and cancer health effects. For non-cancer effects, a threshold, below which no adverse effects occur, is assumed. The first step for non-cancer effects is to determine the point of departure (POD) using the available animal and/or human data, i.e., the no observed adverse effect level (NOAEL), the lowest observed adverse effect level (LOAEL), or the percent effect using benchmark dose modeling (BMD). The point of departure is divided by the applicable uncertainty factors (UF; interspecies, intraspecies, LOAEL to NOAEL, subchronic to chronic, and database) to determine the reference dose (RfD) or reference concentration (RfC). As an alternative to the RfD or RfC, a margin of exposure (MOE) can also be calculated. The MOE is calculated by dividing the POD by an exposure estimate and is compared against a composite UF (i.e., a Level of Concern). As the MOE increases, risk decreases.

The hazard dose-response assessment for cancer outcomes assumes a linear risk in most instances unless the data indicate otherwise; it is assumed there is no threshold level at which the pollutant does not increase excess lifetime cancer risk. The slope of the dose-response curve is used to estimate cancer risk. For carcinogens acting via a mutagenic MOA without chemical-specific data, age-dependent adjustment factors (ADAFs) are used to adjust for age at exposure in lifetime cancer risk or risk during a specific portion of a lifetime. As an example, Brenda noted the benzo[a]pyrene (B[a]P) Integrated Risk Information System (IRIS) Assessment conducted in 2017, which found that the relative contribution to B[a]P's lifetime cancer risk from earlier life stages of 0 to <2 years of age and 2 to <16 years of age is higher compared to the adult life stage. Combined, the 0 to <2 and 2 to <16 years age groups contributed 53% of the lifetime total cancer risk.

Brenda also discussed the FQPA safety factor, which incorporates the intraspecies, interspecies, LOAEL to NOAEL, subchronic to chronic, and database UFs in addition to special FQPA concerns, including the following:

- Comparative sensitivity in young.
- Residual uncertainties in exposure of infants and children.
- Residual uncertainties in toxicity of infants and children that is not accounted for by the database UF.

In the exposure assessment, the source, media, and route of exposure are determined, and a quantitative assessment of external exposure (vs. internal dose) is conducted using direct measures or modeled estimates. The life stage-specific considerations in the context of exposure assessment include the following:

- Physiological.
    - Oxygen consumption and breathing zone.
    - Food and water consumption per body weight.
    - Height, weight, and surface area.
- Behavioral and environmental.
    - Time spent near ground and touching surfaces.
    - Time spent indoors, outdoors, school, and daycare.
    - Time spent doing activities (sports, bathing, or swimming).

    - Non-dietary ingestion (dust, soil, nonfood items).
    - Dietary food preferences and nutrition.
- Children's products.
- Unique early life pathways.
    - Breast milk.
    - Crawling.
    - Mouthing behaviors.

EPA provides guidance on selecting age groupings for exposure assessments in the Agency's 2005 publication "Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants." It is important to standardize age group selection to make comparisons and to ensure life stage specific variables are considered. For instance, Brenda discussed an example that demonstrated how dramatically drinking water ingestion rates vary when fine-grained age groups (e.g., 0 –1 month, 1–3 months, 3–6 months, 6–12 months, 1–2 years, 2–3 years, 3–6 years, 6–11 years, 11–16 years) are measured.

The final step, risk characterization, integrates exposure assessment, hazard identification, and dose-response information to fully depict health risks. EPA's risk characterization policy maintains that risk characterization should be transparent, clear, consistent, and reasonable regarding the nature and presence (or absence) of risks, how the risk was assessed, where assumptions and uncertainties still exist, and where policy choices will need to be made. Risk characterizations usually contain a qualitative discussion of risk, even if it is not assessed quantitatively.

Following Brenda's presentation, CHPAC members raised the following points:

- A CHPAC member asked a question about the CHPAC's TSCA letter. He asked for clarification on the 2005 Agency guidance on early life exposures to carcinogens. The CHPAC had cited it as an example of one of the documents that provided appropriate ADAFs when doing TSCA risk evaluations, especially in the context of children's health risk assessment. He asked if he heard Brenda correctly that the document is only relevant to cancer outcomes. Brenda responded that it is, in fact, only relevant to outcomes with a mutagenic mode of action. The member asked what the Agency is doing in the context of TSCA. Brenda responded that only a subset of chemicals are both carcinogenetic and have a mutagenic mode of action. She added that most TSCA chemicals will not have the ADAF, because they will not meet both of these criteria. Some TSCA chemicals will and are published in the IRIS database. The member also pointed out that the CHPAC recommended the use of the FQPA factors as an example of what actions the Agency could take, though he acknowledged their current restriction to assessments of pesticides. Brenda agreed that the FQPA factor is a special circumstance, but noted that many of its applications are covered in other UFs as well. For instance, a lack of data on reproductive and developmental impacts could be covered by using the database uncertainty factor.
- Another member followed up by asking why the FQPA factor is so special. He noted that Congress mandated its use because it is important and wondered why it is not used as the rule rather than the exception. Another member noted that only applying the additional uncertainty factor in pesticide risk assessment is odd because pesticides are typically more data rich than other chemicals in commerce. A third member pointed out that children are often an afterthought or not considered at all, so having any special consideration is a step in the right direction.
- A member asked if there is a standardized risk assessment for children by developmental stage. He wondered if the same algorithms could be used by practitioners to determine if, for example, a woman should be breastfeeding or not, or if she should be using formula with bottled versus tap

water. He noted that EPA regulates individual chemicals, but the goal is to break the exposure. Brenda acknowledged that the EPA regulatory framework and the public health and clinical practice approaches are very different. She noted that there has been progress and increased conversations, but there is more work to do in this area.

- A member made several comments related to integration of endocrine screening, presented by Stan Barone, into the regulatory framework. Currently, regulatory decision making revolves around a POD, so the challenge will be shifting this paradigm. Next, she noted that UFs may need to be updated, since the factor of 10 is somewhat arbitrary and may be too large or too small in certain cases. Finally, she commented on the fact that the regulatory system is based on an assessment of one chemical at a time. Brenda acknowledged that she presented on the traditional risk assessment approach. She added that the framework will likely change. Brenda also noted that regulatory approaches are typically not the source of cutting-edge science, but EPA does want to incorporate these advances, which is why she underscored the iterative nature of the process. She also agreed that UFs are the source of much debate.
- A member commended EPA's tremendous progress in the context of children's health risk assessment, but urged the group to look toward the future. No one is exposed to a single chemical; multiple exposures represent the reality of environmental exposures. He would like to see EPA and researchers at other organizations begin to explore interactions between multiple exposures and how they act as a group to affect human health. A second member voiced her agreement. She noted that, in most cases, the Agency describes that type of work as a cumulative risk assessment. She added that EPA has had a number of efforts related to cumulative risk assessment, but said it is difficult in practice. It is difficult primarily due to the fact that it includes so many factors, but also because Agency researchers cannot reach consensus on the definition. Within the Office of Pesticide Programs (OPP), cumulative risk assessment is narrowly defined as pesticides that act via the same mode of action. So an OPP cumulative risk assessment would not even incorporate all pesticides, let alone other types of chemicals. On the other side, she pointed out that some experts advocate for the inclusion of all chemical stressors in addition to the full suite of social stressors as well. Brenda stated that cumulative risk assessment is a topic of interest at EPA, and it is being discussed, as it is not only a children's health issue. But for the time being, Agency scientists have to do what they can using incremental progress on a giant problem.
- A member commented that the California Environmental Protection Agency (CalEPA) does not consider mutagenic modes of action differently than other carcinogens. CalEPA applies age-specific safety factors for early life exposure in cancer risk assessment regardless of mechanism of action.
- A member asked if qualitative descriptions of risk would be used in a regulatory context. Brenda noted that the qualitative discussions are part of the risk characterization, while regulatory decisions are made in the risk management context. She said the two decision contexts are slightly different, and typically more than one factor is considered in risk management.
- A member asked for clarification on how OCHP is involved in reviewing risk assessments conducted in other parts of the Agency and how the office comments on these documents. Brenda replied that in OCHP's small regulatory and science policy support group, there are two pesticide review committees. OCHP also participates in three TSCA chemical-specific workgroups. And there are a number of regulations that OCHP is involved with through the Action Development Process. Through this, OCHP is involved in a number of risk assessments. Some programs only use children-specific defaults if they are considering a children's health outcome, but will use the general population assumption (e.g., 70 kg man) if it is a health outcome that could occur in

children or adults. Some programs have built into their legislation a review process under which these assumptions are reviewed more frequently and are updated more often.

- A member noted that children's exposures to chemicals typically occur through products (i.e., by mouthing, household dust, indoor air, etc.). She asked if those pathways will be incorporated into the new TSCA assessments. Brenda responded that she is not certain which of these pathways are relevant to each of the first ten TSCA chemicals, but she suspects that an attempt will be made by EPA researchers to incorporate them when applicable.

VI. Public Comment

Claire Barnett, Healthy Schools Network, discussed the two American Public Health Association polices that were adopted in November 2017. The first policy, which had been circulated to the CHPAC members, is a comprehensive framework that Claire described as a useful tool for the committee. Claire also suggested reading the second policy on establishing environmental public health systems for children at risk or with exposures in school settings. Claire added that the Healthy Schools Network in collaboration with the Children's Environmental Health Network cohosted a national workshop on eliminating lead in schools and childcare facilities. The report from the workshop was published on April 4, 2018. The general message of the report was to prevent lead exposure in children before elevated blood lead levels are observed. Claire concluded her comment by recommending that the updated Federal Strategy should address eliminating lead in school and childcare facilities. She added that there should be adequate resources supplied to support the Federal Strategy, especially in areas of poverty.

VII. EPA's Contribution to the Federal Strategy to Reduce Childhood Lead Exposures and Associated Health Impacts

Hayley Hughes, EPA National Lead Coordinator, gave an overview of the Federal Lead Strategy. She began by noting the tremendous progress the country has made in reducing childhood blood lead levels (BLLs). Since the late 1970s, the median childhood BLL has decreased by 95%. Based on data from the CDC's National Health and Nutrition Examination Survey (NHANES), median BLLs among 1–5 year old children dropped from 15 µg/dl in 1976–1980 to 0.7 µg/dl in 2013–2014. EPA regulations related to leaded gasoline and household paints have facilitated this decrease, though scientific understanding of the health impacts of elevated BLLs has also been further refined over time.

In May 2012, CDC's Advisory Committee on Childhood Lead Poisoning Prevention recommended the use of a reference range to identify elevated BLLs based on the 97.5th percentile of the NHANES data. The current CDC reference value for children's BLLs is 5 µg/dl, and it is estimated that around 250,000 children have elevated BLLs.

The President's Task Force on Environmental Health Risks and Safety Risks to Children was established by Executive Order 12898 in 1997. It is co-chaired by the EPA Administrator and the Department of Health and Human Services (HHS) Secretary. The first Federal Lead Strategy identified eliminating health hazards from leaded paint as a public health priority. In January 2018, the Task Force agreed to a collaborative, cross-agency approach to address childhood lead exposure. The senior steering committee is finalizing the draft plan to reduce childhood lead exposure, which will be submitted to the Office of Management and Budget (OMB) for review. The draft strategy emphasizes reducing disproportionate health impacts of lead exposure concentrated among racial minority and low-income populations.

Additionally, as part of EPA's commitment to reducing childhood lead exposures, Administrator Pruitt announced the availability of as much as $5.5 million in loans though the Water Infrastructure and Finance Innovation Act. The program provides funding for states and municipalities to provide clean and safe drinking water by addressing lead exposure in drinking water systems and to repair and rehabilitate

aging infrastructure systems. Lead service lines and corrosion of lead fixtures are the most common sources of lead in drinking water.

As the EPA Lead Coordinator, Hayley's role is to collaborate and coordinate EPA headquarters and regional offices, state, local, and tribal efforts related to reducing lead exposure.

Following Hayley's presentation, CHPAC members raised the following points:

- A member asked if there will be a public comment period on the draft Federal Lead Strategy. Ruth Etzel noted that there was a public comment period from November 2017 to February 2018, and EPA considered the 700+ comments into the latest draft.
- James Roberts noted that the Children's Environmental Health Network and its Executive Director, Nse Witherspoon, would be happy to partner with EPA on its lead work.
- Tom Neltner added that he would be happy to connect Hayley with partners at the Environmental Defense Fund or others in the fields of healthy housing and lead paint.
- Ellen Braff-Guajardo echoed other CHPAC member's commitment to helping EPA along its goal to eradicating childhood lead exposure.
- A member asked if EPA is conducting stakeholder outreach. Hayley confirmed EPA is reaching out to stakeholders related to the Federal Lead Strategy. Ruth added that those activities are dependent on the outcome of OMB's review. The member raised his concern that there may not be a comment period after the draft is released in June because there is so much work to be done so quickly. He also asked how the Federal Lead Strategy interacts with the Lead and Copper Rule. Hayley did not have specific details, but stated she would provide an answer to Ruth, who can distribute the response to the CHPAC.
- A member asked if EPA is conceptualizing the decreases in terms of elimination or reduction. She noted that framing it as eradication is especially important for minority and low-socioeconomic status communities. Hayley acknowledged that EPA is reviewing all of the comments to this effect and will frame the strategy in terms of what is achievable over the plan's 5-year timeframe.
- A member asked if the EPA Administrator and the HHS Secretary plan to meet again to formally approve the final strategy. Ruth Etzel, Director of the Office of Children's Health Protection said that when the co-chairs last met, they expressed their intention to hold another meeting.

VIII. Update on Conducting Research in Puerto Rico after Hurricane Maria

Gredia Huerta-Montanez, Investigator, Puerto Rico Testsite for Exploring Contamination Threats (PROTECT), presented on conducting research in Puerto Rico seven months after Hurricane Maria. She began by reviewing the destruction caused by Hurricane Maria, noting the collapse of the electrical, water, telecommunication, and road systems. In addition, many homes were destroyed. The recovery effort was described as Federal Emergency Management Agency's (FEMA) most challenging mission ever.

Gredia then provided an update on Puerto Rico seven months after Hurricane Maria. She described how FEMA has received over one million aid applications, but many home owners were denied assistance because they lacked formal home ownership documentation. Gredia added that the road system and electrical grid have not yet been fully repaired, which has caused some communities and businesses to become isolated. She discussed the issue of water safety in Puerto Rico noting that the old and leaky water systems cause large water losses in the distribution process and are susceptible to contamination. In addition, because tap water has been unreliable, increased bottled water consumption has led to a higher volume of trash.

Since the destruction caused by Hurricane Maria, Puerto Ricans have struggled with mental illnesses including post-traumatic stress disorder, anxiety, and depression. Gredia also noted that the education system has been affected by the hurricane as well. After the hurricane, schools were destroyed, served as shelters, or were forced to run without electricity or clean water. The mental health and education system problems have been further complicated by an exodus of medical professionals, students, and teachers to the United States. Gredia explained that the Center for Puerto Rican Studies at the City University of New York estimated that approximately 14% of the Puerto Rican population will leave the island by the end of 2019.

Gredia then described the research efforts and public policy changes that have occurred since Hurricane Maria that provide Puerto Ricans hope for the future. There has been an increased awareness of environmental health issues, an application of scientific research to improve the quality of life for all, an advocacy for environmental health and children's health protection, and promotion of water safety. Gredia also touched upon the efforts of her research group to increase the preparedness of the island for potential disasters. Gredia added that her research group is continuing to act as a community center of support, participating in disaster response and preparedness orientations, and educating families and health care professionals on environmental health issues.

José Cordero, Head, Department of Epidemiology and Biostatistics, College of Public Health, University of Georgia continued the presentation by describing how the most pressing needs of Puerto Rican communities changed after the hurricane. After the hurricane, there was a larger need for transportation, housing, food security, and communication for Puerto Rican communities.

José then noted the resilience shown by some of the research institutions on the island. The University of Puerto Rico Medical Sciences Campus; Puerto Rico Science, Technology and Science Trust; and Molecular Science Building provided reliable generators to medical centers and internet access to local business owners. Medtronic set up satellite phones on their campus for community members to contact their families and provided meals for their employees and surrounding neighbors. Finally, local pharmacies developed systems to transport important medications to people who did not have access to reliable transportation.

José then said that despite some of the successes, there are still many forgotten communities that are waiting for the basic elements of recovery. He added that there is a need to develop plans and protocols for future disasters. Gredia concluded the presentation by discussing how the spirit and sense of hope is beginning to fade in many families in Puerto Rico because of the delayed recovery effort. However, she added that it is never too late for individuals to step out of their comfort zones and help the most vulnerable and susceptible members of the population.

Following José and Gredia's presentation, CHPAC members raised the following points:

- One CHPAC member asked if José and Gredia have had a chance to talk with disaster preparedness groups. José said that they are working closely with several disaster preparedness groups. He also plans to work with research groups on the island to develop a set of articles describing the post-disaster experience and lessons learned.
- A member asked if there have been any data collection efforts to help guide public health responses during future disasters. José replied that the problem lies in the combination of not having enough data and not using correctly the data that are currently available. He added that they are developing an Institute of Public Health in Puerto Rico to increase data collection and analysis.
- A CHPAC member inquired about the use of solar panels on the island. Gredia said that there are discussions about using solar panels on the island, but the plans have not yet been implemented.

IX. Pediatric Environmental Health Specialty Unit (PEHSU): New York State Model

Joel Forman, Associate Professor, Icahn School of Medicine at Mount Sinai, presented on the New York State model of the Pediatric Environmental Health Specialty Unit (PEHSU). He began by reviewing the national PEHSU network, which was formed in 1998 and is funded by ATSDR, EPA, and the states. Multidisciplinary academic centers in each EPA region are sponsored with funding of approximately $125,000–150,000 per year. PEHSUs consult with families, health care providers, and local public health agencies; develop education and materials for providers and the public; support disaster response; and provide professional training among other activities. The challenge of the PEHSU network is to serve distant regional populations on small budgets by supporting local providers who do not feel they have sufficient training in children's environmental health.

New York State has initiated a 12-year effort to establish a statewide network. Phase 1 began with a $40,000 grant from the New York State Assembly in 2005, after which services were supported by annual add-on appropriations from the New York State Committee on Environmental Conservation. Efforts were hampered 2009–2013 due to a gap in funding. The PEHSU received another add-on appropriation in 2014, but experienced another funding gap in 2015. Joel noted that the insights gained during Phase 1 included the critical need for both a formal needs assessment and stable funding.

In 2013, the Children's Environmental Health Center at Icahn School of Medicine at Mount Sinai produced a detailed needs assessment that estimated the costs of environmental disease to the state and mapped environmental threats by county. The center continued to advocate for funding through the state legislature, but also sought to develop a relationship with the governor's office in hopes of integrating funding for the PEHSU into the state's annual budget. To this end, they coordinated a group to meet with the governor's office as a united front multiple times. Individuals from a number of organizations participated, including the Icahn School of Medicine at Mount Sinai, University of Rochester Medical Center, Stony Brook School of Medicine, Children's Hospital Albany Medical Center, University of Buffalo Jacobs School of Medicine and Biomedical Sciences, Northwell Health, Maria Fareri Children's Hospital, The Children's Hospital at Montefiore, Upstate Medical University. The PEHSU also had numerous partnerships in its advocacy venture, which included EPA, ATSDR, the New York State Department of Health, the New York City Department of Health, American Academy of Pediatrics (AAP), New York State Pediatric Advocacy Coalition, WE ACT for Environmental Justice, Clean and Healthy New York, Healthy Schools Network, and LSA Family Health Services. Joel noted that the coordinated group effort was critical to gain traction in the governor's office.

In 2016, the New York State Governor's Annual Budget Request included the statewide PEHSU network. New York State appropriated $1 million to the New York State Environment Protection Fund budget, which funds projects that protect the environment and enhance communities. An additional $1 million was added to the appropriation by the New York State Legislature. In 2017, funding was increased to a $10 million, 5-year appropriation, and the New York State Department of Health selected the Icahn School of Medicine at Mount Sinai to act as the network's coordinating center. Joel summarized the campaign's success factors as bringing everyone (i.e., academics, advocates, clinicians, politicians) together, building relationships strategically, and conveying local needs.

The new network, called the New York State Center of Excellence (COE) in Children's Environmental Health, is currently in its first quarter of operation. The overall goals of the program include the following:

- Acting as a resource for all New York State children, their families, and providers in aspects of environmental health.
- Improving access to expertise in pediatric environmental health.

- Improving the recognition and management of environmental health problems, including lead exposure, in children.
- Providing comprehensive, coordinated services for children exposed to environmental toxins throughout development.
- Reducing environmental health threats to children where they live, play, and learn through partnerships, educational campaigns, and public health marketing.
- Preventing disease in children through partnerships, educational campaigns, and public health marketing.
- Increasing the accuracy of diagnosis of diseases in children caused by environmental factors.
- Improving the treatment of diseases in children caused by environmental factors.
- Strengthening and expanding educational programs in environmental health for children.
- Better quantifying and describing the burden on children from diseases of environmental origin.

The network is comprised of several centers, which focus on different areas of work. The core areas of the network are education and training, health care community consultations, public health marketing, and community partnerships. The center at Mount Sinai focuses on education and training. The center has worked to incorporate environmental health into primary care through the use of an e-screener application, has existing efforts to incorporate training into pediatric residency programs at multiple locations, and engages school health professionals and tribal communities. The COE has also initiated a 2-year Pediatric Environmental Health Scholars Program for both clinicians and non-clinicians for which the curriculum is being set. The program already has four applicants for 2018 program year.

Consultations with healthcare professionals are led by the centers at Rochester, Syracuse, Albany, and Mount Sinai through collaborations with the non-profit MotherToBaby and the AAP's Project ECHO. The centers at Westchester and Mount Sinai emphasize clinical consultations and prioritize inpatient screenings, outpatient visits, and telehealth. The center at Westchester launched its direct clinical center in the fall of 2017 and has already had 32 direct referrals.

The Long Island center focuses on public health marketing and has formalized relationships with the Huntington Breast Cancer Action Coalition, two school districts, and a residential treatment facility coalition. Additionally they launched the NY State COE in Children's Environmental Health website.

Due to time constraints, Barbara asked the CHPAC members to hold their questions and thanked Joel for his insightful presentation.

X. Children's Environmental Health Indicators at EPA: America's Children and the Environment

Dan Axelrad, Environmental Scientist, EPA Office of Policy, presented on children's environmental health indicators at EPA. He began by introducing America's Children and the Environment (ACE), which is EPA's compilation of key indicators of children's health and the environment. Dan explained that the third and most recent edition of ACE (ACE3) was released in January 2013. He added that the first edition of ACE was released in December 2000, the second edition of ACE was released in February 2003, and the website, which houses periodic indicator updates, was initiated in 2005.

Dan provided a brief overview of ACE, noting that there are three main categories of indicators: environments and contaminants, biomonitoring, and health. He added that there is a desired set of characteristics for each indicator. Ideally, each indicator has current population-based data, is national in scope, portrays a data series over time, and can be stratified by demographic characteristics.

Dan then reviewed the source of the indicator data and the topics covered in ACE3 for each of the indicator categories. For the environments and contaminants category, the indicator data are primarily supplied by EPA databases and the topics included criteria air pollutants, indoor environments, and chemicals in food. For the biomonitoring category, the underlying data came mainly from NHANES and the topics included lead, PCBs, and perchlorate. Finally, for the health category, the data came mainly from HHS surveys and National Center for Health Statistics databases and the topics included respiratory diseases, obesity, and adverse birth outcomes. Dan also presented an indicator figure for each category.

Dan discussed the supplementary topics covered in ACE3. The supplementary topics are topics of interest that lack nationally representative data and/or continuing data collection. He highlighted both birth defects and contaminants in schools and child care facilities as important supplementary topics. Dan concluded his presentation by noting that the indicators have been maintained and updated on the ACE website since the release of ACE3. He included a list of the topics that have been updated since the last report, which included drinking water contaminants, mercury, and neurodevelopmental disorders.

Following Dan's presentation, CHPAC members raised the following points:

- Several CHPAC members asked if the underlying data for the indicators is available, specifically the data broken down by race, ethnicity, and socioeconomic status. Dan said that the underlying data for the indicators is available on existing online databases. He added that the data tables for some indicators broken down by race, ethnicity, and socioeconomic status are available on the ACE website for the most recent data (2012–2015).
- A CHPAC member asked for clarification on the data collection methods to measure asthma prevalence. Dan responded that in the health interview survey, the mothers are first asked if their child has ever been diagnosed with asthma. If the mother responds yes, additional follow up questions are asked.
- One member inquired if there are any plans to examine drinking water contaminant levels further. Dan said that he would like to be able to recreate for drinking water what already exists for air quality. However the data source available to ACE is the Safe Drinking Water Information System, which does not contain data on the concentration of the contaminants measured in the drinking water.
- A member asked if the Department of Education's database containing information on the renovation history and age of school buildings was included in the report. Dan answered that the data from the Department of Education's database was not included in the report.
- One member noted that based on the indicator figure, asthma attacks seem to be decreasing but ADHD cases are continuing to rise. The member asked why there has not been as much success at getting to the root of the rising neurocognitive impacts of environmental exposures. Dan said that the potential relationships between biomonitoring indicators and ADHD is complex. He added that the knowledge of those potential relationships is still being developed.
- A CHPAC member asked how the ACE data compare to the Healthy People 2020 and NHANES data reports. Dan explained that Healthy People 2020 is a goals-oriented effort that is independent of ACE. He added that a major difference between NHANES reports and ACE is that NHANES does not break out data for women of childbearing age, while ACE does.
- A member asked if ACE would consider examining soil vapor contaminants. Dan responded that ACE would be interested in examining soil vapor contaminants, but a national data source is not available.
- Several CHPAC members noted the value of ACE as a resource and commended Dan on his hard work.

XI. Office of Children's Health Protection Update

Ruth Etzel, Office Director, EPA Office of Children's Health Protection, presented an update of the OCHP activities. See Appendix B for a detailed overview of the OCHP Update.

XII. Wrap Up

Barbara Morrissey, CHPAC chair, thanked the CHPAC members for their attendance and active participation during the meeting. Barbara thanked OCHP staff for putting together a great meeting.

U.S. Environmental Protection Agency
CHILDREN'S HEALTH PROTECTION ADVISORY COMMITTEE
April 19–20, 2018

Holiday Inn Capitol
550 C Street SW, Washington, DC

Agenda

Meeting Objectives

- Review and discuss CHPAC letters, "Highest Priorities for Childhood Lead Exposure Prevention" and "Protecting Children's Health under Amended TSCA."
- Receive an update on the novel approaches and progress in EPA's Endocrine Disruptor Screening Program (EDSP) from the life-stage perspective.
- Hear about the Centers for Disease Control and Prevention's work on eliminating lead risks.
- Build an understanding of EPA's children's health risk assessment efforts.
- Understand EPA's contributions to the development of the Federal Strategy to Reduce Childhood Lead Exposures and Associated Health Impacts.
- Receive an update on research being conducted in Puerto Rico after Hurricane Maria.
- Learn about the Pediatric Environmental Health Specialty Unit (PEHSU) New York state model.
- Gain an understanding of children's environmental health indicators at EPA: America's Children and the Environment.
- Listen to an update on EPA's Office of Children's Health Protection activities.

Thursday, April 19, 2018

9:30 – 10:00	**REGISTRATION**
10:00 – 10:10	**Welcome** Ruth Etzel, Director, EPA Office of Children's Health Protection
10:10 – 10:30	**Introductions and Review of the Agenda** Barbara Morrissey, CHPAC Chair
10:30 – 11:00	**Review of Past CHPAC Letters: "Highest Priorities for Childhood Lead Exposure Prevention" and "Protecting Children's Health under Amended TSCA"** Barbara Morrissey, CHPAC Chair Discussion
11:00 – 12:00	**Overview and Update of Novel Approaches in EPA's Endocrine Disruptor Screening Program (EDSP) with an Emphasis on Life Stages** Stan Barone, Acting Director, EPA Office of Science Coordination and Policy Discussion
12:00 – 1:30	**LUNCH –** on your own; a list of nearby restaurants is available.
1:30 – 3:00	**Lead Elimination: CDC/ATSDR Activities** Sharunda Buchanan, Acting Director, Office of Priority Projects and Innovation (OPPI) in the Immediate Office of the Director (IOD) in CDC's National Center for

	Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR) Discussion
3:00 – 3:20	**BREAK**
3:20 – 4:20	**Children's Health Risk Assessment** Brenda Foos, Director, Regulatory Support and Science Policy Division, EPA Office of Children's Health Protection Discussion
4:20 – 5:00	**Public Comment**
5:00 – 5:30	**Wrap-Up**
5:30	**ADJOURN**

Friday, April 20, 2018

8:30 – 9:00	**REGISTRATION**
9:00 – 9:30	**EPA's Contribution to the Federal Strategy to Reduce Childhood Lead Exposures and Associated Health Impacts** Hayley Hughes, EPA National Lead Coordinator Discussion
9:30 – 10:00	**Update on Conducting Research in Puerto Rico after Hurricane Maria** José Cordero, Head, Department of Epidemiology and Biostatistics, College of Public Health, University of Georgia Gredia Huerta-Montanez, Investigator, Puerto Rico Testsite for Exploring Contamination Threats (PROTECT) Discussion
10:00 – 10:30	**Pediatric Environmental Health Specialty Unit (PEHSU): New York State Model** Joel Forman, Associate Professor, Icahn School of Medicine at Mount Sinai Discussion
10:30 – 10:50	**BREAK**
10:50 – 11:35	**Children's Environmental Health Indicators at EPA: America's Children and the Environment** Daniel Axelrad, Environmental Scientist, EPA Office of Policy Discussion
11:35 – 12:05	**Office of Children's Health Protection Update** Ruth Etzel, Director, EPA Office of Children's Health Protection Discussion
12:05 – 12:30	**Wrap-Up** Barbara Morrissey, CHPAC Chair
12:30	**ADJOURN**

Children's Health Protection Advisory Committee
Office of Children's Health Protection Updates
(as of 3/31/18)

PRESIDENT'S TASK FORCE ON ENVIRONMENTAL HEALTH RISKS AND SAFETY RISKS TO CHILDREN

- On February 15, 2018, EPA Administrator Pruitt held a Principals meeting with members of the *President's Task Force on Environmental Health Risks and Safety Risks to Children* to discuss the development of a "Federal Strategy to Reduce Childhood Lead Exposures and Eliminate Associated Health Impacts."
- Members of the Task Force agreed that addressing childhood lead exposure is a priority for their agencies/departments and agreed on the five goals within the Strategy.

EPA'S CHILDREN'S HEALTH NEWS & ANNOUNCEMENTS

- In response to Administrator Pruitt's vision for a collaborative multi-federal agency approach to reduce childhood lead exposure across the country, EPA Region 8 (R8) created a Lead Strategy that identifies specific areas for engagement with federal, state, tribal and local partners. Programmatic areas of focus include Drinking Water, Lead-Based Paint, Superfund, Brownfields, Response and the Resource Conservation and Recovery Act (RCRA). A R8 cross program lead strategy implementation team was recently formed and is meeting to finalize the Strategy, establish specific commitments and the communication plan.
- The EPA Schools website epa.gov/schools now has a Disaster Preparedness and Recovery Resources section.
- **Dr. Leon Guo**, M.D., M.P.H., Ph.D., the current Director of Taiwan's National Institute for Environmental Health Sciences spoke at the Office of Children's Health Protection on April 3rd, 2018. Dr. Guo presented on the research in Taiwan surrounding health investigations of phthalates and actions to protect children's health.
- **EPA Settles with Amazon for Distributions of Illegal Pesticides:** In February 2018, EPA announced an agreement with Amazon to protect the public from the hazards posed by unregistered and misbranded pesticide products. In August 2015 and January 2016, EPA issued FIFRA Stop Sale, Use, or Removal Orders against Amazon Services LLC to prohibit the sale of illegal pesticide products that can easily be mistaken for black-board or side-walk chalk, especially by children. After receiving the stop sale orders, Amazon immediately removed the products from the marketplace, prohibited foreign sellers from selling pesticides, and cooperated with EPA during its subsequent investigation. The orders, as well as EPA's subsequent engagement with the company, prompted Amazon to more aggressively monitor its website for illegal pesticides. As a result, Amazon has created a robust compliance program comprised of a sophisticated computer-based screening system backed-up by numerous, trained staff. In October 2016, Amazon notified all customers who purchased the illegal pesticides between 2013 and 2016 to communicate safety concerns with these products and urge disposal. Amazon also refunded those customers the cost of the products, approximately $130,000. Under the terms of this recent agreement, Amazon will pay an administrative penalty of $1,215,700 and will develop an online training course on pesticide regulations and policies that will be mandatory for all entities planning to sell pesticides on Amazon.com. This settlement is intended to prevent children from being inadvertently exposed to illegal pesticides, particularly those mimicking chalk. For more information on this settlement or to read a copy of the consent agreement and final order, go to: https://www.epa.gov/enforcement/amazon-services-llc-fifra-settlement.
- The EPA Office of Pollution Prevention and Toxics' (OPPT) is currently developing a proposed rule regarding Dust Lead Hazard Standards, which identify dangerous levels of lead in paint,

dust, and soil. It also provides benchmarks on which to base remedial actions that help safeguard children from the adverse health effects of childhood lead exposure. OCHP is supporting workgroup efforts to develop technical approaches to evaluate children's health exposures and develop lead hazard standards.

PUBLIC COMMENT OPPORTUNITIES

- **Draft Human Health Risk Assessments for Pesticide Registration Reviews for Public Comment by April 30, 2018.** Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. As part of the registration review process, the Agency has completed comprehensive draft human health and/or ecological risk assessments for a number of pesticides. Please note that only children's health concerns are highlighted here. For more information, see: https://www.gpo.gov/fdsys/pkg/FR-2018-02-27/pdf/2018-03986.pdf.
    - Acetamiprid is a neonicotinoid insecticide registered for use on fruit and vegetable crops and in a number of residential sites, including indoor application as a crack/crevice/bedbug treatment, applications to gardens, and pet (i.e., dogs) spot-on treatment. The acute dietary analysis is just below the level of concern for children 1<2 years old, as is the aggregate risk assessment. Using developmental toxicological endpoints, certain occupational uses result in estimated risks of concern. For the Draft Human Health Risk Assessment for Acetamiprid, see: https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0329-0025.
    - Butralin is an herbicide used as a plant growth regulator on tobacco. There are no dietary or spray drift risks of concern for children. The Agency has considered the exposure to humans from residues in tobacco smoke by assessing the short-term inhalation exposure and risks for adults only. For the Draft Human Health Risk Assessment for Bifenthrin, see: https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0384-0247.
    - Cypermethrins are pyrethroid insecticides registered for use on a wide variety of agricultural food/feed crops, livestock, and sod farms; at recreational sites (i.e., golf courses, athletic fields); at indoor residential sites, on residential lawns; on gardens and trees; on mosquitoes and termites, and on pets. There are estimated risks of concern for children from certain uses on lawns, indoors, and pet collars. For the Draft Human Health Risk Assessment for the Cypermethrins, see: https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0720-0020.
    - Glyphosate is an herbicide used on fruit, vegetable, and field crops, turf, and aquatic application scenarios. There are no dietary, residential or spray drift risks of concern for children. In response to concern from segments of the general public related to the presence of glyphosate in human milk, the EPA analyzed human milk samples collected by the National Children's Study for residues of glyphosate and its metabolites; there were no detection in the 39 samples from 39 mothers. EPA has determined glyphosate to be "Not likely to be carcinogenic to humans." For the Draft Human Health Risk Assessment for Glyphosate, see: https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0068. For the Analysis of Human Milk for Incurred Residues of Glyphosate and its Metabolites, see https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0085.
    - Prometon is an herbicide used in non-agricultural and non-residential locations, including parking lots, roadsides, and under pavement. When using modeling data, drinking water estimates are of concern for children; however, when using monitoring data there is no concern. Spray drift estimates require a 10-foot buffer from the field edge. For the Draft

Human Health Risk Assessment for Prometon, see: https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0068-0019.

- Pymetrozine is an insecticide used in agricultural field and orchard/vineyard crops, on Christmas trees and ornamentals, and interior plantscapes. Acute and chronic dietary risk estimates, mainly from drinking water, are of concern for children. EPA has classified Pymetrozine as a "likely human carcinogen". For the Draft Human Health Risk Assessment for Pymetrozine, see: https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0368-0017.

UPCOMING EVENTS & WEBINARS

- Region 8 is coordinating a session at the National Green Schools Conference and Expo May 4, 2018. The conference session is titled, "Extreme Weather and Natural Disasters: Supporting Schools Plan and Recover." Presenters from state, local, federal government and research organization will present on how schools play an important role during disasters. Presenters will provide lessons learned as well as consideration of emotional needs during and after disaster.

U.S. Environmental Protection Agency
CHILDREN'S HEALTH PROTECTION ADVISORY COMMITTEE
April 19–20, 2018

Members Present

Ellen Braff-Guajardo	Sierra Health Foundation	Sacramento	CA
Rebecca Bratspies	CUNY School of Law	Long Island City	NY
Lori Byron	Indian Health Service–Crow Agency (Retired)	Billings	MT
Jose Cordero	College of Public Health, University of Georgia	Athens	GA
Caroline Cox	Center for Environmental Health	Oakland	CA
Joel Forman	Department of Pediatrics, Icahn School of Medicine at Mount Sinai	New York	NY
Maeve Howett	University of Massachusetts Amherst	Amherst	MA
Gredia Huerta-Montanez	PROTECT	Guaynabo	PR
Maureen Little	NYC Department of Health and Mental Hygiene	New York	NY
Mark Miller	California Environmental Protection Agency; University of California, San Francisco	San Francisco	CA
Barbara Morrissey	Washington State Department of Health	Olympia	WA
Olga Naidenko	Environmental Working Group	Washington	DC
Tom Neltner	Environmental Defense Fund	Washington	DC
Greg Ornella	Sherwin-Williams Company	Cleveland	OH
Stephen Owens	Squire Patton Boggs (US) LLP	Phoenix	AZ
Rubin Patterson	Howard University	Washington	DC
James Roberts	Medical University of South Carolina	Charleston	SC
Deanna Scher	Minnesota Department of Health	Saint Paul	MN